



#2 ——— October, 2004

Bulletin & Update

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

*The Committee for the Protection of Human Subjects (CPHS) will periodically release issues of the **Bulletin & Update** to inform researchers and others regarding important changes in CPHS procedures as well as State and National issues of importance for human subject protection in research. Copies of the **Bulletin & Update** will be distributed via e-mail to researchers as well as posted on the CPHS web site (www.oshpd.ca.gov/cphs).*

CPHS has developed a new bill of rights for human subjects participating in non-medical research. Research projects that do not include medical experimentation should utilize this new form, which was developed to be more appropriate to the needs of subjects participating in social science research.

Participant's Bill of Rights for Non-Medical Research

You have been asked to participate in a research study. Any participant in a research study has the right to:

- (a) Be told the nature and purpose of the study.
 - (b) Be given an explanation of what will happen during the study and of how the research participant is expected to participate.
 - (c) Be given an explanation of any risks or discomforts that may be experienced as a result of participating in the study.
 - (d) Be given an explanation of any benefits that may be expected from participation in the study.
 - (e) Be told of other appropriate choices that may be better or worse than being in the study, and be told of the risks and benefits of those other choices.
 - (f) Have the opportunity to ask questions about the study or about your participation in it, both before agreeing to participate in the study and during the course of the study.
 - (g) Be told that you may withdraw your consent and participation in the study at any time, and that your withdrawal will not affect your services.
 - (h) Be told that you may refuse to answer any question.
 - (i) Be given a copy of the signed and dated consent form.
 - (j) Be free of pressure when considering whether to consent to, and participate in, the study.
 - (k) Be informed, upon request, about the results of the study.
-

CPHS Members

Larry L. Dickey, MD, MPH, MSW (Chair)

Chief, Office of Clinical Preventive Medicine
California Department of Health Services

Lois Lowe, PhD (Vice Chair)

Research Specialist, Retired

Fernando Cordero, PhD

Psychologist
Santa Maria Mental Health Services

Howard L. Harris, PhD

Associate Professor, California State
University, Sacramento, and
Dean, Cosumnes River College, Retired

Patricia M. Kirkish, PhD, MA

Consulting Psychologist
California Department of Mental Health

Richard J. Ko, PharmD, PhD

Research Scientist
Food and Drug Branch
California Department of Health Services

Steven Lubeck, PhD, MS

Research Scientist Supervisor
Healthcare Quality and Analysis Division
Office of Statewide Health
Planning & Development

R. J. Mihordin, MD

Staff Psychiatrist
Forensic Services Branch
California Department of Mental Health

Millard A. Murphy, JD

Prison Law Office
University of California, Davis

Edward M. Opton, Jr., PhD, JD

Office of the General Counsel
University of California

Juan D. Ruiz, MD, DrPH, MPH

Epidemiology Branch
Office of AIDS
California Department of Health Services

Kurt P. Snipes, PhD, MS

Chief, Cancer Planning,
Research, and Disparities Section
Cancer Control Branch
California Department of Health Services

CPHS Staff

Roxana Killian, LCSW

Administrator

Joan Mock

Assistant Administrator

1600 9th Street, Room 432

Sacramento, CA 95814

Tel. (916) 653-0176

Fax (916) 651-6222

cphs-mail@oshpd.ca.gov

Research projects involving medical experimentation are required to continue using the traditional version of the bill of rights, which has now been renamed the Participant's Bill of Rights for Medical Research. The California Health and Safety Code, Section 24174, defines medical experimentation as:

- (a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject.
- (b) The investigational use of a drug or device
- (c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject.

Both medical and non-medical versions of the bill of rights and their Spanish translations are available on the CPHS website (www.oshpd.ca.gov/cphs) as Appendix III and IV, respectively, of the Instructions for Researchers.

HIPAA Waivers of Patient Authorization

CPHS is empowered to grant waivers of patient authorization for release of protected health information under the Health Insurance Portability and Accountability Act (HIPAA). Unfortunately, at least 50% of the requests that CPHS currently receives for such waivers are unnecessary because the data sources are not considered "covered entities" under HIPAA. The Office of Statewide Health Planning and Development (OSHPD) is not a covered entity under HIPAA and OSHPD databases are not considered protected health information under HIPAA. Similarly, some Department of Health Service's databases collected for public health surveillance are not subject to HIPAA. Researchers are advised to check with departmental data sources regarding HIPAA applicability before requesting waivers of patient authorization from CPHS.

HIPAA waivers of patient authorization must be renewed annually at each periodic review. Researchers are required to submit a statement as to whether there have been any breeches or changes in data security that might affect continuation of the waiver. Check the CPHS web site for more detailed instructions.

Reminder to Check the CPHS Web Site

In the last few months, several of our forms and some portions of our Instructions for Researchers have been revised. Please be sure to check the web site before filing applications for both new and continuing projects.